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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,599	02/28/2002	Brent R. Constantz	CRD5401USNP	7922

27777 7590 04/15/2009
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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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04/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/087,599	Applicant(s) CONSTANTZ ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25-54 is/are pending in the application.
- 4a) Of the above claim(s) 35-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment filed on 1/12/09 has been entered.

Claims 1-23, 25-34 are present for examination.

Claims 35-54 are withdrawn.

Claim 24 is cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-104, 17-20, 21, 23, 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Robertson (US 4.344.434).

Regarding claims 1-6, 9-10, 12-14, Robertson discloses a device for localized contact of a fluid to a target physiological site, said device comprising:

(a) a fluid delivery element 34 having a proximal and distal end;

(b) a an unobstructed, compliant porous region 40 at said distal end of said fluid delivery element through which fluid must flow to contact said a target physiological site, the porous region being formed from a compliant material and the fluid tube connected with inlet lumen 20/22 to make flush juxtaposition with the target physiological site; and

(c) an aspiration element (col. 12, lines 41-45).

Regarding claims 11 and 17, the device further comprises a second fluid delivery element 36.

Regarding claims 18-20, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., "...configured to conform to a vascular structures such as a valve sinus or aortic sinus" functional limitations, does not impose any structural limitation upon the

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claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Regarding claim 21, Robertson discloses the invention substantially as claimed as discussed above. The porous fluid flow path is capable to fit inside of an aortic sinus of said aortic valve; the porous fluid flow path is capable of contacting the aortic valve.

It has been held that the recitation that porous fluid flow path is “capable of” performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Regarding claims 23, 25-26, 28, Robertson further discloses that a shunt element 200; a plug 100. As noted that, Applicant defines that plug is as a covering of porous material that covers the porous tip (para [0075]). Similarly, the membrane 100 is performing same function as the plug of claimed invention.

Claims 1-6, 9-14, 17-20, 21, 23, 25-28 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (US 5,407,423).

Regarding claims 1-6, 9-10, 12-14, Yoon discloses a device for localized contact of a fluid to a target physiological site, said device comprising:

- (a) a fluid delivery element 10 having a proximal and distal end;
- (b) a an unobstructed, compliant porous region 18 at said distal end of said fluid delivery element through which fluid must flow to contact said a target physiological site, the porous region being formed from a compliant material and the fluid tube 42 connected with inlet lumen 106 to make flush juxtaposition with the target physiological site; and
- (c) a fluid control means is a syringe and act as an aspiration element for removing fluid from the resilient foam material 104 and the cylindrically shaped chamber within the hollowed-out central area 102 to establish a vacuum/aspiration (col. 8, lines 44+).

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Regarding claims 11 and 17, the device further comprises a second fluid delivery element 68 (Fig. 13).

Regarding claims 18-20, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., "...configured to conform to a vascular structures such as a valve sinus or aortic sinus" functional limitations, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Regarding claim 21, Yoon discloses the invention substantially as claimed as discussed above. The porous fluid flow path is capable to fit inside of an aortic sinus of said aortic valve; the porous fluid flow path is capable of contacting the aortic valve.

It has been held that the recitation that porous fluid flow path is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Regarding claim 22, a separate porous fluid flow path such as 118 in Fig. 30).

Regarding claims 26, 28, Yoon further discloses that a shunt element 134 (Fig. 33); a plug/elastic membrane 120/124. As noted that, Applicant defines that plug is as a covering of porous material that covers the porous tip (para [0075]). Similarly, the membrane 120/124 is performing same function as the plug of claimed invention.

Regarding claims 27, Yoon discloses the invention substantially as claimed as discussed above. Yoon further discloses a cap element 138.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 22, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson in view of von Dyck (US 6,033,390).

Robertson discloses the invention substantially as claimed. Robertson does not disclose the device comprises a separate porous fluid flow path; a cap element proximal to the porous fluid flow path.

Von Dyck discloses similar device with separate porous fluid flow paths 216 (Fig. 13), as noted that these fluid flow path is capable of flowing each different aortic sinus of the aortic valve; a cap element 128 proximal to the porous fluid flow path.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Robertson with a cap and separate porous fluid flow paths, as taught by von Dyck, in order to delivery drugs at different locations and the cap for protecting the device.

Claims 7-8, 15-16, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Yoon.

Yoon discloses the invention substantially as claimed. Robertson does not disclose the device includes an external energy application element. However, Applicant admitted on page 13 of Specification that it is well-known in the art to provide the means of applying external energy for delivering ultrasound to physiological sites.

Claims 23, 25, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Yoon in view of Suresh et al. (US 6,951,555).

Regarding claims 23, 25, 31-32, Yoon discloses the invention substantially as claimed. Yoon does not disclose the device includes an occlusion element.

Suresh discloses that a catheter 750 is used to perfuse, and balloon member 752 occludes the aorta above an aortic valve 16, as illustrated in FIG. 7d, col. 10, lines 1-10.

As known that, device of Yoon is a multifunction device and used at an operative site of cavity body, therefore, one skill in the art would recognize that the device can be used as a catheter adapted to be inserted into body vessels or into the aorta as well.

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It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Yoon with occlusion element in order to occlude the aorta valve.

Regarding claims 33-34, similar to rejection of claims 7-8, 15-16 and 29-30 above.

Response to Arguments

Applicant's arguments with respect to claims 1-23, 25-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763